

## REMARKS

Claims 1-50 have been cancelled. New claims 51-77 have been added.

The support for the new claims may be found throughout the specification, including the following pages:

Claims 51-53, pg. 7, lines 23-35, to pg. 11, lines 1-21

Claim 54, pg. 6, line 25, page 8, lines 17-22, and page 9, lines 15-19

Claim 55, pg. 7, lines 23-35

Claims 56 – 58, pg. 7, lines 28-32

Claim 59 – 62, original claim 9

Claim 63, original claim 10

Claim 64 – 65, pg. 8, lines 8-10, pg. 9, lines 10-12, pg. 19, lines 12-19, and original claim 10

Claim 66, original claim 12

Claim 67, pg. 8, lines 8-10, pg. 9, lines 10-12, pg. 19, lines 12-19, and original claim 10

Claim 68, pg. 8, lines 8-10, pg. 9, lines 10-12, and pg. 19, lines 12-19

Claim 69, pg. 8, lines 8-10, pg. 9, lines 10-12, and pg. 19, lines 12-19

Claim 70, original claim 12

Claim 71, original claims 10 and 11

Claim 72 – 77, original claim 13

Claims 51-77 are pending. The specification has been amended to include the claim of priority. No new matter has been added.

**Rejection under 35 USC § 112, second paragraph:**

The Examiner rejected claim 18 under 35 USC § 112, second paragraph, for being indefinite and for failing to point out and distinctly claim the subject matter which Applicants regard as their invention.

Specifically, the Examiner has rejected claim 18, as terms “said first interfering component” and “the deviation” contained insufficient antecedent basis. This ground of rejection is moot in view of the cancellation of claim 18. Moreover, this rejection should not be applied to new method claim 51 as each element of new claim 51 now contains the proper antecedent basis.

Also, the Examiner has rejected claim 18 as being unclear as symbols (1,1), (1, n), and (d1) have not been defined in the claim. This ground of rejection is moot in view of the cancellation of claim 18. Furthermore, this ground of rejection should not be applied to new claim 51 as the meaning of the subscripts (1,1), (1,n), and (d1) is clear and these symbols are often used by those of ordinary skill in the art for characterizing various physical characteristics. For example, subscripts (1,1) and (1,n) are used for representing the lower and upper boundaries of a first wavelength range. For example,  $E_d$  is defined as predetermined approximation function, in one instance a predetermined first approximated function, hence  $E_{d1}$  (claim 51 and specification at page 8, last two

lines). Therefore, Applicants believe that the definition of such subscripts in the claim is not necessary.

Next, the Examiner rejected claim 18 as being unclear, as the term "fitting being" is not clear whether it is "first extinction spectrum" or "approximated spectrum." This ground of rejection is moot in view of the cancellation of claim 18. Furthermore, this ground of rejection should not be applied to new claim 51, as new claim 51 now recites "fitting of said first approximated spectrum  $\bar{E}_1(\lambda)$  to said first measured extinction spectrum  $E_1(\lambda)$  being performed by varying said concentration  $C_H$  of hemoglobin and said coefficients  $a_{0h}, a_{1h}$ , so that a deviation between said first measured extinction spectrum  $E_1(\lambda)$  and said first approximated spectrum  $\bar{E}_1(\lambda)$  is minimized in order to determine the concentration  $C_H$  of hemoglobin."

Accordingly, the Examiner's rejection under § 112, second paragraph should not be applied to new claim 51.

**Rejection under 35 USC § 102(b):**

Claims 18-43 have been rejected under 35 USC § 102(b) as being anticipated by Witte et al. (U.S. Patent No. 4,267,572). More specifically, the Examiner has asserted that Witte et al. disclose a method for determining the concentration of the components of a sample, including measuring a first extinction spectrum of the sample in a first selected wavelength, fitting an approximated spectrum considered to be reconstructed from the corrective

values and standard spectra to the first measured spectrum, wherein the approximated spectrum is a combination of predetermined approximate function for background and a predetermined extinction spectrum of a first pure component. According to the Examiner, in the method of Witte et al. the fitting approximated spectrum is being performed by varying the concentration of a first interfering component and at least two coefficients, so that a deviation between the first measured spectrum and the approximated spectrum is minimized for determining the concentration of the first interfering component and the first selected wavelength range being selected so that the concentration of the first interfering component can be determined. The Examiner concluded that Witte's method anticipates the present invention. This ground of rejection is moot in view of the cancellation of claims 18-43.

Furthermore, this ground of rejection should not be applied to new claims 51-77, as new claims 51-77 are directed to a method of measuring a concentration of hemoglobin and bilirubin in a sample of blood serum or blood plasma before analysis of the sample by an in vitro diagnostic method. The method is designed to determine whether an amount of hemoglobin, bilirubin or lipid present in the sample can interfere with a measurement of a target analyte contained in the sample by means of the diagnostic method. The method of measuring a concentration of hemoglobin and bilirubin in a sample includes sequentially determining the concentration of hemoglobin in the sample, and then determining the concentration of bilirubin in the sample.

As a first point of distinction, Witte et al. do not teach determining a concentration of interfering components, hemoglobin and bilirubin, and determining the contribution of lipid to the extinction of a blood plasma sample before the sample is analyzed by means of an in vitro diagnostic analysis method. Rather, Witte et al. teach a method of determining concentration of undefined components in a sample. In contrast, claims 51-77 of the present invention define specific interfering components such as hemoglobin and bilirubin to be determined by the method of the instant invention.

Witte et al. also do not teach a method that employs a sequential determining of the concentration of the interfering components. Rather Witte et al. teach a method that employs an iterative algorithm for calculating the concentration of all components of the test solution simultaneously in a single step process (Witte et al., column 5, lines 12-20). Applicants' invention teaches a method of measuring a concentration of hemoglobin and bilirubin in a sample that includes sequentially determining the concentration of hemoglobin and bilirubin in the sample. More specifically, according to the method defined by claim 51, the concentration of the first component (hemoglobin) is calculated in the first step of the method, and the concentration of the second component (bilirubin) is determined in the second step, which also takes into account the concentration of the first component as determined in the first step of the Applicant's method. Therefore, claim 51 should not be anticipated by the cited reference.

Claims 52-77 depend from claim 51 and are thus likewise should not be anticipated. Moreover, each of these dependent claims recites additional elements that make it further patentable over the cited reference.

For example, referring to claim 53, Witte et al. do not teach a method that includes obtaining a differential spectrum representative of the amount of lipid present in the sample.

Also, as to claim 54, Witte et al. do not teach a method therein the fitting of the approximated spectra to the measured values of extinction spectra is done by a last squares fitting method.

In addition, referring to claims 56, 57, and 58, Witte et al. do not teach the differential spectrum being computed over a wavelength range covering about 30%, 50%, and 100% respectively, or more of the whole wavelength range defined by the broadest combination of the first wavelength range defined by  $\lambda_{1,1}$  and  $\lambda_{1,n}$ , and the second wave length range defined by  $\lambda_{2,1}$  and  $\lambda_{2,n}$ .

For these reasons, the Witte et al. reference would not have anticipated Applicants' invention defined by the independent claim 51, or any of the claims that depend therefrom.

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## CONCLUSION

Applicants submit that the present application is now in condition for allowance. If, for any reason, the Examiner feels that an interview would be helpful to resolve any remaining issues, he is respectfully requested to contact the undersigned attorney at (312) 321-4235.

Respectfully submitted,

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